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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,415	10/15/2003	Kenneth McCadden	McCADDEN ET AL. - 1	6848
7590 07/14/2005 COLLAR & ROE, P.C. 1077 Northern Boulevard Roslyn, NY 11576-1696			EXAMINER CHONG, YONG SOO	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,415	MCCADDEN ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/15/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Application

Claims 1-16 are pending and are examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for the method of treating an alcohol induced hangover, does not reasonably provide enablement for *preventing*. The specification does not enable any person skilled in the art to which it pertains to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7)

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the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention, which pertains to a method of treating and preventing an alcohol induced hangover.

(2) State of the Prior Art: The state of the art regarding treating an alcohol induced hangover is relatively high, however the state of the art for the prevention of an alcohol induced hangover is relatively low.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the prevention, inhibition, and treatment of an alcohol induced hangover.

(4) Guidance of the Specification: The guidance of the specification as to the prevention of alcohol induced hangovers is completely lacking. The specification discloses methods of treating alcohol induced hangovers, however there is no mention of how one is able to prevent the onset of an alcohol induced hangover in a subject, in the absence of treatment. Moreover, the specification fails to mention the complete prevention or cessation of an alcohol induced hangover once the onset of preclinical evident stage is determined.

(5) The Predictability or Unpredictability of the Art: The invention is directed to a method of treating, inhibiting, and preventing an alcohol induced hangover. The specification does not disclose how one of ordinary skill in the art at the time of the invention would be able to prevent an alcohol induced hangover, nor does the prior art reveal any type of prevention associated with an alcohol induced hangover.

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(6) The Relative Skill of those in the Art: Currently, the only known method of preventing alcohol induced hangovers is to not drink alcohol.

(7) Working Examples: The specification does not give any data for the prevention of an alcohol induced hangover.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the prevention of an alcohol induced hangover. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Herschler et al. (US Patent 4,514,421).

Herschler et al. teach the use of methylsulfonylmethane (MSM) as a method of treating headache (col. 10, lines 11-12), migraine (col. 7, lines 4-5), nausea (col. 2, lines 12-14), dizziness (col. 11, lines 32-36), and body aches (col. 6, line 62 to col. 7, line 2).

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All of these well-known effects are inherent to symptoms of alcohol-induced hangovers, as stated in applicant's disclosure. Methylsulfonylmethane can be administered orally in any convenient manner, e.g., by ingesting the crystalline MSM or an aqueous solution thereof. Tablets, dragee, capsules, or pills as such or in admixture with the usual pharmaceutically acceptable excipients, diluents, tableting aids are also preferred (col. 3, lines 17-24). Such aqueous solution is exemplified where MSM is dissolved in water (col. 10, lines 21-22) or juice (col. 11, lines 8-11) prior to administration to a patient. Total daily dosages of MSM are from 10 to 5,000 mg. (col. 2, line 68 to col. 3, line 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8 are rejected under 35 U.S.C. 103(a) as being obvious over Herschler et al. (US Patent 4,514,421) as applied to claims 1-6.

The instant claims are directed to a method of treating an alcohol related hangover with an amount of methylsulfonylmethane in a bottle, box, carton, package or envelope.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to encase an amount of MSM in an enclosed container for the following reasons. Firstly, if not packaged, MSM may degrade as a

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result of exposure to environmental factors such as light and oxidizing agents.

Secondly, packaging MSM will confer many useful benefits such as storage and shipping. Thirdly, it is easier to quantize a consistent amount of MSM in a package so that one knows exactly how much MSM is being attained. Lastly, MSM in liquid form is amorphous thus requiring a container of some sort in which it can be administered.

A person of ordinary skill in the art would have been motivated to package MSM because of degradation concerns, convenience, and out of necessity resulting from MSM being in liquid form.

Conclusion

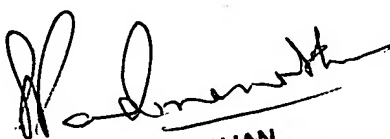
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER